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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/009,873	11/01/2002	Anand Ranganathan	SHW-009US	4622
959	7590	01/03/2006	EXAMINER	
LAHIVE & COCKFIELD, LLP. 28 STATE STREET BOSTON, MA 02109			LU, FRANK WEI MIN	
			ART UNIT	PAPER NUMBER
			1634	
DATE MAILED: 01/03/2006				

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/009,873	Applicant(s) RANGANATHAN, ANAND	
	Examiner Frank W. Lu	Art Unit 1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 October 2005.
 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-48 is/are pending in the application.
 4a) Of the above claim(s) 18-20 and 22-48 is/are withdrawn from consideration.
 5) ☐ Claim(s) _____ is/are allowed.
 6) ☒ Claim(s) 1-17 and 21 is/are rejected.
 7) ☐ Claim(s) _____ is/are objected to.
 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
 10) ☒ The drawing(s) filed on 01 November 2002 is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☒ All b) ☐ Some * c) ☐ None of:
 1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
 * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>12/01 and 2/02</u> . | 6) <input checked="" type="checkbox"/> Other: <u>Notice for sequencing listing.</u> |

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of Group I, claim 1-21 and species (1) (claim 17) in the reply filed on October 12, 2005 is acknowledged. The traversal is on the ground(s) that "The inventions of Groups I-V all relate to means for assembling DNA units in sequence. As such the searches with regard to these inventions would be co-extensive and would not involve a serious burden on the Examiner".

The above argument has been fully considered and has not been found persuasive toward the withdrawal of the restriction requirement nor persuasive toward the relaxation of same such that Groups I to V will be examined together. First, as shown in previous office action, the restriction is not based on the search burden on the Examiner but is dependent on that Groups I to V lack the same or corresponding special technical features. Second, applicant does not argue why Groups I to V do not lack the same or corresponding special technical features. Therefore, the requirement is still deemed proper and is therefore made FINAL and claims 1-17 and 21 will be examined.

Sequence Rules Compliance

2. This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). For example, see pages 26-28 and 40 of the specification. However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 for the reason(s) set forth on the attached

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Notice To Comply With Requirements For Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures.

Direct the reply to the undersigned. Applicant is requested to submit a statement to PTO that the content of the paper and computer readable copies are the same and no new matter is added and return a copy of the attached Notice to Comply with the reply.

Specification

3. This application does not contain an abstract of the disclosure as required by 37 CFR 1.72(b). An abstract on a separate sheet is required.
4. The disclosure is objected to because of the following informalities: there are four nucleotide sequences with more ten nucleotides in Figures 6. BRIEF DESCRIPTION OF THE DRAWINGS in the specification does not describe these nucleotide sequences and these nucleotide sequences do not have SEQ ID Nos.

Appropriate correction is required.

Claim Objections

5. Claims 4 and 10 are objected to because of the following informalities: (1) "an Xba1" should be "a XbaI"; and (2) "Xba1" should be "XbaI".
6. Claim 9 is objected to because of the following informality: "claims 1 to 4" should be "any one of claims 1 to 4".
7. Claim 9 is objected to because of the following informality: "io" in step a) should be deleted.

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8. Claim 15 is objected to because of the following informality” “in to” in line 2 should be “into”.

9. Claim 17 is objected to because of the following informality: “polyketide synthesising enzyme domain DNA sequences” should be “DNA sequences of polyketide synthesizing enzyme domain”.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

10. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

11. Claims 1-17 and 21 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

12. Claim 1 is rejected as vague and indefinite in view of step a) of the claim because it is unclear what is relationship between the restriction site on the 3' end of each DNA unit and a recognition site for a DNA modification enzyme. Does the restriction site on the 3' end of each DNA unit and a recognition site for a DNA modification enzyme share some nucleotide sequences? Please clarify.

13. Claim 1 recites the limitation “the desired DNA unit” in step c) of the claim. There is insufficient antecedent basis for this limitation in the claim because steps a) and b) only have DNA unit and have no desired DNA unit. Please clarify.

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14. Claim 1 recites the limitation “the ligated product” in step c) of the claim. There is insufficient antecedent basis for this limitation in the claim because steps a) and b) have no ligated product. Please clarify.
15. Claim 1 recites the limitation “the inserted DNA unit” in step c) of the claim. There is insufficient antecedent basis for this limitation in the claim because steps a) and b) have no inserted DNA unit. Please clarify.
16. Claim 3 recites the limitation “the dam methylase” in the claim. There is insufficient antecedent basis for this limitation in the claim because there is no dam methylase in claims 1 and 2. Please clarify.
17. Claim 4 recites the limitation “the desired DNA unit” in step c) of the claim. There is insufficient antecedent basis for this limitation in the claim because steps a) and b) only have DNA unit and have no desired DNA unit. Please clarify.
18. Claim 4 is rejected as vague and indefinite in view of step d) of the claim because it is unclear how to recovering a resulting plasmid since step b) does not limit a starting DNA construct as a plasmid. Please clarify.
19. Claim 6 recites the limitation “the fragment” in the claim. There is insufficient antecedent basis for this limitation in the claim because there is no word “fragment” in claims 1-4. Please clarify.
20. Claim 8 is rejected as vague and indefinite because it is unclear how to replicate the ligated product in a dam- strain of E. coli by means of a suitable vector. Please clarify.

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21. Claims 9 and 10 are rejected as vague and indefinite because it is unclear that “a desired other DNA unit” in step c) or “a desired DNA unit” in step d) are identical to one of other DNA units in step b) or not. Please clarify.

22. Claim 13 is rejected as vague and indefinite because it is unclear that the solid phase is spilt and mixed with what. Please clarify.

23. Claim 15 is rejected as vague and indefinite because it is unclear what means “a host capable of expressing the protein encoded by the vector”. Does this phrase means a host capable of expressing the protein encoded by the DNA units? Please clarify.

Conclusion

24. No claim is allowed.

25. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993)(See 37 CAR § 1.6(d)). The CM Fax Center number is (571)273-8300.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frank Lu, Ph.D., whose telephone number is (571)272-0746.

The examiner can normally be reached on Monday-Friday from 9 A.M. to 5 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones, can be reached on (571)272-0745.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

A handwritten signature in black ink, appearing to read "Frank Lu". The signature is fluid and cursive, with the first name "Frank" being more prominent than the last name "Lu".

Frank Lu
Primary Examiner
December 27, 2005

NOTICE TO COMPLY WITH REQUIREMENTS FOR PATENT APPLICATIONS CONTAINING NUCLEOTIDE SEQUENCE AND/OR AMINO ACID SEQUENCE DISCLOSURES

Applicant must file the items indicated below within the time period set the Office action to which the Notice is attached to avoid abandonment under 35 U.S.C. § 133 (extensions of time may be obtained under the provisions of 37 CFR 1.136(a)).

The nucleotide and/or amino acid sequence disclosure contained in this application does not comply with the requirements for such a disclosure as set forth in 37 C.F.R. 1.821 - 1.825 for the following reason(s):

- ☒ 1. This application clearly fails to comply with the requirements of 37 C.F.R. 1.821-1.825. Applicant's attention is directed to the final rulemaking notice published at 55 FR 18230 (May 1, 1990), and 1114 OG 29 (May 15, 1990). If the effective filing date is on or after July 1, 1998, see the final rulemaking notice published at 63 FR 29620 (June 1, 1998) and 1211 OG 82 (June 23, 1998).
- ☒ 2. This application does not contain, as a separate part of the disclosure on paper copy, a "Sequence Listing" as required by 37 C.F.R. 1.821(c).
- ☒ 3. A copy of the "Sequence Listing" in computer readable form has not been submitted as required by 37 C.F.R. 1.821(e).
- ☐ 4. A copy of the "Sequence Listing" in computer readable form has been submitted. However, the content of the computer readable form does not comply with the requirements of 37 C.F.R. 1.822 and/or 1.823, as indicated on the attached copy of the marked -up "Raw Sequence Listing."
- ☐ 5. The computer readable form that has been filed with this application has been found to be damaged and/or unreadable as indicated on the attached CRF Diskette Problem Report. A Substitute computer readable form must be submitted as required by 37 C.F.R. 1.825(d).
- ☐ 6. The paper copy of the "Sequence Listing" is not the same as the computer readable form of the "Sequence Listing" as required by 37 C.F.R. 1.821(e).
- ☐ 7. Other: _____

Applicant Must Provide:

- ☒ An initial or substitute computer readable form (CRF) copy of the "Sequence Listing".
- ☒ An initial or substitute paper copy of the "Sequence Listing", as well as an amendment directing its entry into the specification.
- ☒ A statement that the content of the paper and computer readable copies are the same and, where applicable, include no new matter, as required by 37 C.F.R. 1.821(e) or 1.821(f) or 1.821(g) or 1.825(b) or 1.825(d).

For questions regarding compliance to these requirements, please contact:

For Rules Interpretation, call (703) 308-4216

For CRF Submission Help, call (703) 308-4212

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